

**Written Comments of the Generic Pharmaceutical Association to the Joint
Committee on Public Health on HB 5307**

Submitted by

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March 1, 2010

Senator Harris, Representative Ritter, and Members of the Joint Committee, the Generic Pharmaceutical Association (GPhA) is pleased to have this opportunity to submit written comments in connection with your hearing on HB 5307. This legislation would create a needless barrier to the substitution of generic epilepsy medicines—products that FDA has repeatedly confirmed to be equally as safe and effective as their brand equivalents. For the reasons set forth below, GPhA urges you to oppose this bill.

Current Connecticut law already provides prescribers with a simple means of requiring a pharmacist to dispense a specific brand of medicine by merely specifying “BRAND MEDICALLY NECESSARY” on the prescription pad.¹ This legislation would seriously hinder the substitution of more affordable generic equivalents for Connecticut consumers. Particularly when health care costs are soaring, requiring a more costly brand product to be dispensed even when a generic becomes available is both unnecessary and needlessly burdensome to the patient, the state, and the health care system as a whole.

It is important to recognize that scientific authorities have consistently affirmed the equal safety and effectiveness of generic drugs. In a recent letter to the Iowa Pharmacy Association, FDA specifically addressed concerns with switching brands of epilepsy medications, stating that “[the agency] is aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products [and] [t]o date [FDA] has no scientific evidence that demonstrates a particular problem with this group of products.”²

Regarding bioequivalent products more broadly, FDA recently posted the following statement on the agency website:

“FDA recently evaluated 2,070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs into a person’s body. These studies were submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name was only 3.5 percent. Some generics were absorbed slightly more, some slightly less. This amount of difference would be expected and

¹ CONN. GEN. STAT. § 20-619(c) (2010).

² Letter from Gary Buehler, Director, Office of Generic Drugs, FDA, to Iowa Pharmacy Association, January 11, 2008.

acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name”³ (emphasis added).

FDA noted further regarding narrow therapeutic index (NTI) drugs, in a letter to the National Boards of Pharmacy that “because of FDA’s strict bioequivalence criteria, we believe that drugs do not fall into discrete groups that would allow one to consider NTI drugs as being clearly different from other drugs for purposes of therapeutic substitution.”⁴ Indeed, FDA has consistently affirmed its long held position that:

“If one therapeutically equivalent drug is substituted for another, the physician, pharmacist, and patient have FDA’s assurance that the physician should see the same clinical results and safety profile . . . [and that] any differences that could exist should be no greater than one would expect if one lot of the innovator’s product was substituted for another.”⁵

There is no good reason to create an indiscriminate barrier to generic substitution, which HB 5307 seeks to put in to effect.

Not only has FDA weighed in decisively on this issue, but the American Medical Association has also remarked that “[while] concerns still persist among some prescribers about the therapeutic equivalence of generic NTI drugs to their brand name innovator products, scientific evidence to support these concerns either does not exist or is extremely weak.”⁶ In fact, an article published recently in the Journal of the American Medical Association “*Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease*” broadly addresses generic substitution of narrow therapeutic index drugs and urges that:

“[to] limit unfounded distrust of generic medications, popular media and scientific journals could choose to be more selective about publishing perspective pieces based on anecdotal evidence of diminished clinical efficacy or greater risk of adverse effects with generic medications. Such publications may enhance barriers to appropriate generic drug use that increase unnecessary spending without improving clinical outcomes.”⁷

³ U.S. Food and Drug Administration, Facts and Myths about Generic Drugs, *available at* <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm>.

⁴ Letter from Roger Williams, Deputy Center Director for Pharmaceutical Science, FDA, to National Association of Boards of Pharmacy, April 16, 1997, *available at*, <http://www.fda.gov/cder/news/ntiletter.htm>.

⁵ Letter from Stuart Nightengale, Associate Commissioner of FDA, to Health Care Practitioners, “Therapeutic Equivalence of Generic Drugs,” January 28, 1998 *available at*, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm073182.htm>.

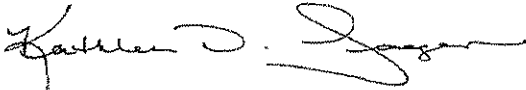
⁶ Council on Science and Public Health, American Medical Association, Report 2-A-07, “Generic Substitution of Narrow Therapeutic Index Drugs” (2007).

⁷ JAMA “Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease A Systematic Review and Meta-analysis” Kesselheim et al. December 2, 2008.

Imposing needless barriers to generic substitution would also increase costs to consumers, the state and the health care system. As noted recently by AARP, "researchers have found that patients who initiate therapy with lower-cost generic medications have higher rates of adherence, making them appealing to providers who want to ensure treatment compliance and avoid unnecessary spending."⁸ Not only do obstacles to generic substitution have serious fiscal impact, but such policies also inflict considerable consequences on patients and public health in general by making medicine less affordable.

GPhA would be happy to answer any questions or provide further explanation that would be helpful to the Committee. Thank you for considering our industry's views as you address this matter.

Sincerely,



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⁸ AARP Public Policy Institute, *Strategies to Increase Generic Utilization and Associated Savings*, available at, http://assets.aarp.org/rgcenter/health/i16_generics.pdf, (December, 2008).